K130281

JUN 21 2013

510(k) Summary

Summary Preparation Date: May 15th, 2013

1. **Submitted By**

Oak Ridge Products L.L.C.
4612 Century Court
McHenry, Illinois, 60050 USA
Establishment Registration #:1419823

2. **Contact Information (Primary)**

Tibor B. Kovari
Quality Assurance Manager
Oak Ridge Products L.L.C.
4612 Century Court
McHenry, Illinois, 60050 USA
(815) 363-4700
tkovari@oakridgeproducts.com

Contact Information (Secondary)

Conor J. O'Malley
Owner
Oak Ridge Products L.L.C.
4612 Century Court
McHenry, Illinois, 60050 USA
comalley@oakridgeproducts.com
(815) 363-4700

3. **Device identification:**

Trade Name:	Oak Ridge Products Sharps Containers
Common Name:	Sharps Container
Product Code:	MMK
Classification:	Accessory to hypodermic single lumen needles
CFR Reference:	21 CFR 880.5570 – Class II
Classification Panel:	General Hospital

OAKRIDGE PRODUCTS

4. Predicate devices:

Trade Name:	B-D Guardian™ Nestable Sharps Collectors
Common Name:	Sharps Container
Product Code:	MMK
Classification:	Accessory to hypodermic single lumen needles
CFR Reference:	21 CFR 880.5570 – Class II
Classification Panel:	General Hospital

Legally Marketed Equivalent Devices:

Company	Product	510(k)#
Becton Dickinson	B-D Guardian™ Nestable Sharps Collectors	K943575
Covidien (originally cleared under Sage Products now owned by Covidien)	Multi-purpose Sharps Container	K943659
Covidien (originally cleared under Sage Products now owned by Covidien)	SharpSafety™ Phlebotomy Containers	K943660

5. Product Description:

The Oak Ridge Products Sharps Containers are an injection molded polypropylene plastic designed for a single-use. The containers are puncture resistant, leak resistant on the sides and bottom, closable and stable. The products have engraved maximum fill lines on the containers and instructions for locking the container closed. Labels are white with black text and a black bio-hazard symbol printed on an orange-red background. Labels are adhered to the containers at the time of manufacture with the fill line warning matching the engraved fill line on the container.

The Oak Ridge Products Sharps Containers are made of three parts (a base, a lid, and a closure) that form a single unit. Parts are nested together to reduce storage and shipping requirements. The bases are offered in natural (translucent) or colored (red). These are available in three sizes; 1) 1 quart Phlebotomy, 2) 5.4 quart for Patient room and 3) 2 gallon containers. Lids and closures are uncolored translucent material. The translucent nature of the product allows for a visual determination of content level.

General Specifications Table

Part Number	Product Description	Access opening size	Access opening and Closure	Overall Size L x W x H (inches)	Weight (grams)	Capacity at full line
0310-1500	1 Quart Phlebotomy RED	2.0" x 1.5"	Slide	4.5x4.5x7.5	115 grams	.8 quarts
0354-1100	5.4 quart Universal Clear	8" x 1.4"	Rotating Door	11x4.5x10.5	340 grams	4.3 quarts
0354-1500	5.4 quart Universal RED	8" x 1.4"	Rotating Door	11x4.5x10.5	340 grams	4.3 quarts
0320-1500	2 Gallon Nestable RED	5.6" x 2.3"	Slide	10.3x7x710.1	363 grams	7.2 quarts

Accessories

Oak Ridge Products offers a mountable locking bracket for the 1 quart Phlebotomy container. Oak Ridge Products part number #1010-9904.

Oak Ridge Products also offers several wall mountable locking accessories for the 5.4 quart container.

Manufacture	Part Number
Oak Ridge Products	"Press and Click" Locking Wall Bracket with Key #1054-1300
Oak Ridge Products	"Swing Arm" Locking Wall Bracket #1054-7300
Oak Ridge Products	Locking Wall Cabinet #1054-5300

All of the Oak Ridge Products Sharps Containers conform to the recognized standard ASTM F2132-01(2008) for needle puncture resistance. These also meet or exceed the OSHA 1910.1030 recommendations for sharps containers.

6. Indications for Use:

Part Number	Product Description	Access opening size	Access opening and Closure	Length (in)	Width (in)	Height (in)	Mounting
0310-1500	1 Quart Phlebotomy RED	2.0" x 1.5"	Slide	4.5"	4.5"	7.5"	Bracket required
0354-1100	5.4 quart Universal Clear	8" x 1.4"	Rotating Door	11"	4.5"	10.5"	Bracket required
0354-1500	5.4 quart Universal RED	8" x 1.4"	Rotating Door	11"	4.5"	10.5"	Bracket required
0320-1500	2 Gallon Nestable RED	5.6" x 2.3"	Slide	10.3"	7.0"	10.1"	Free Standing

Oak Ridge Products Sharps containers are single-use, disposable, non-sterile containers intended to be used for healthcare purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets, and blood needles. The target population is for trained healthcare professionals.

The 1 quart Phlebotomy container is intended to be used with an appropriate mounting device.

The 5.4 quart is intended to be used with an appropriate mounting device.

The 2 gallon container is intended to be used in areas where there is no unsupervised patient access.

7. Comparison to Predicate Devices:

Manufacturer	Oak Ridge Products	Becton Dickson®	Covidien®	Covidien®
Trade Name	Oak Ridge Products Sharps Containers	B-D Guardian™ Nestable Sharps Collectors	SharpsSafety 'PHLEBOTOMY SHARPS DISPOSAL CONTAINERS'	Multi-purpose Sharps Container 'ANCILLARY AND LARGE VOLUME SHARPS DISPOSAL CONTAINERS'
510(k) number	K130281	K943575	K943660	K943659
Indication for use	Oak Ridge sharps containers are intended to be used for the safe disposal of hazardous sharps	B-D sharps containers are intended to be used for the safe disposal of hazardous sharps	containers are intended to be used for the safe disposal of hazardous sharps	containers are intended to be used for the safe disposal of hazardous sharps
Target Population	Healthcare professional	Healthcare professional	Healthcare professional	Healthcare professional
Where used	Healthcare facilities	Healthcare facilities	Healthcare facilities	Healthcare facilities
Material	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Sharps access	Sharps inserted through the top	Sharps inserted through the top	Sharps inserted through the top	Sharps inserted through the top

Manufacturer	Oak Ridge Products	Becton Dickson®	Covidien®	Covidien®
Sharps closure	Closure feature is closed then locked in place for removal	Flaps are closed and locked in place for removal	Closure feature is closed then locked in place for removal	Closure feature is closed then locked in place for removal
Impact resistance	Yes	Yes	Yes	Yes
Puncture resistance	Yes	Yes	Yes	Yes
Leak resistance	Yes	Yes	Yes	Yes
Single use	Yes	Yes	Yes	Yes
Non-sterile	Yes	Yes	Yes	Yes
Capable of maintaining a stable, upright position	Yes	Yes	Yes	Yes
No features to bend, break, or shear needle.	No Feature Present	No Feature Present	No Feature Present	No Feature Present
Reusable Sharps Containers	Same	Labeling is "Single Use Only"	Labeling is "Single Use Only"	Labeling is "Single Use Only"
Overfill Indication	Same	"Do Not Overfill" or "Fill to this Level Only" is Labeled or embossed on the container at the location of the overfill. Labeling includes a "Fill Line".	"Do Not Overfill" or "Fill to this Level Only" is Labeled or embossed on the container at the location of the overfill. Labeling includes a "Fill Line".	"Do Not Overfill" or "Fill to this Level Only" is Labeled or embossed on the container at the location of the overfill. Labeling includes a "Fill Line".
Clarity	Same	Each Collector has a minimum of one translucent component, either base or top.	Each Collector has a minimum of one translucent component, either base or top.	Each Collector has a minimum of one translucent component, either base or top.
Construction	Same	Injection Molded Containers, Lids and Closure	Injection Molded Containers, Lids and Closure	Injection Molded Containers, Lids and Closure

8. **Substantial Equivalence Discussion of Similarities and Differences:**
   The Oak Ridge Products Sharps Containers are similar to the B-D Guardian™ Nestable Sharps containers in:
   - Intended use
   - Target population
   - Materials
   - Design
   - Performance testing

9. **Intended use comparison:**
   The intended use of the new Oak Ridge Products Sharps Containers is the same as the predicate device. Oak Ridge Products Sharp Containers are containers intended for the disposal of contaminated medical waste in a healthcare facility.

10. **Design and Material Comparison:**
    The design and functional characteristics of the Oak Ridge Products Sharps Containers and the predicate devices are similar. The Oak Ridge Products Sharps Containers parts are nestable and when assembled form a single unit. These units have features to prevent contact between user and the contents and are designed for a visual determination of the maximum capacity. None of the devices have features that bend, break, or shear needles. The devices are designed for a single use by a locking feature in the lids and closure or access door.

    They are constructed of polymeric materials which is injection molded. The Oak Ridge Products Sharps Containers are constructed of only polypropylene. Oak Ridge Products Sharps Containers are either natural (uncolored) or colored red with translucent lids that allow for a visual determination of content level.

11. **Summary of Non-Clinical Performance Bench Testing:**

    11.1 Performance Standards:

    The Recognition Number 6-215 identifies ASTM F2132-01 (reapproved 2008), "Standard Specifications for puncture Resistance of Materials Used for the Collection for Discarded Medical Needles and Other Sharps."

    The Recognition Number 6-293 identifies ISO 23907 First Edition 2012-09-01, "Sharps injury protection - Requirements and test methods - Sharps containers"

    The performance testing demonstrates compliance with the recognized consensus standards, ASTM F2132-01 (reapproved 2008), "Standard Specifications for puncture Resistance of Materials Used for the Collection for Discarded Medical Needles and Other Sharps." and the applicable portions of ISO 23907 First Edition 2012-09-01, "Sharps injury protection - Requirements and test methods - Sharps containers"

    In addition the relevant FDA guidance document, "Guidance on the Content and Format of Premarket Notification [510(k)] Submission for Sharps

Collectors dated October 1993", was used to identify applicable physical and mechanical features of the Oak Ridge Products and predicate devices.

All applicable standards have been used to show that the Oak Ridge Products Sharps Container Family is substantially equivalent to the appropriately listed predicate device.

The performance testing summary demonstrates substantial equivalence between the Oak Ridge Products devices and the predicate devices. The Oak Ridge Products sharps containers have been tested by appropriate methods with respect to the relevant standards, FDA recognized ASTM standards F 2132-01 and OSHA regulations 29 CFR Part 1910:1030. No new issues of safety and effectiveness were raised with the testing performed, and the Oak Ridge Products Sharps containers are considered substantially equivalent to its predicate device.

11.2 Performance Testing (Bench) – Product Testing

The Oak Ridge Products Sharps Containers incorporate equivalent collector design features and performance characteristics.

The results of the product performance testing demonstrated equivalent performance to the predicate device performance and no new issues were raised.

Test Methods:

Puncture Resistance (Performed by and independent materials testing lab) – Passed
ASTM F 2132-01 (2008) "Standard Specification for the Puncture Resistance of Materials used in containers for the Discarded Medical Needles and Other Sharps".

Leak Resistance of bottom and sides – Passed
Based on OSHA Specification 29CFR 1910:1030

Overfill detection and Capacity: – Passed

Needle unwinder and recapper: - Only applicable on 1 quart - Passed

Impact resistance and safe handling – Passed
Based on ISO 23907:2012

Sharps access, closure and minimization of aerosolization : – Passed
Based on ISO 23907:2012

Stability: – Passed
Based on ISO 23907:2012

Mounting Brackets usability and stability: – Passed
Based on ISO 23907:2012

11.3 Performance test summary:

The performance testing summary demonstrates substantial equivalence between the Oak Ridge Products devices and the predicate devices. The Oak Ridge Products sharps containers have been tested by appropriate methods with respect to the relevant standards, FDA recognized ASTM standards F 2132-01, OSHA regulations 29 CFR Part 1910:1030 and ISO 23907:2012(e). No new issues of safety and effectiveness were raised with the testing performed, and the Oak Ridge Products Sharps containers are considered substantially equivalent to its predicate device.

12. Conclusion:

The Oak Ridge Products Sharps Containers introduces no new questions concerning the safety or effectiveness and proves to be substantially equivalent to the respective predicate sharps collectors.

-B-D Guardian™ Nestable Sharps Collector is a registered trademark of Becton, Dickinson and Company.
-BD® is a registered trademark of Becton, Dickinson and Company.
-SharpSafety™ is a trademark of the Covidien Company

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 21, 2013

Oak Ridge Products, Limited Liability Company
C/O Mark Job
Regulatory Technology Services Limited Liability Company
1394 25th Street, N.W.
BUFFALO MN 55313

Re: K130281
Trade/Device Name: Oak Ridge Products Sharps Containers
Regulation Number: 21 CFR 880.5570
Regulation Name: Accessory to hypodermic single lumen
Regulatory Class: Class II
Product Code: MMK
Dated: June 13, 2013
Received: June 14, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use

510(k) Number (if known): K130281

Device Name: Oak Ridge Products Sharps Containers

Model Numbers:

Part Number	Product Description	Access opening size	Access opening and Closure	Length (in)	Width (in)	Height(in)	Mounting
0310-1500	1 Quart Phlebotomy RED	2.0" x 1.5"	Slide	4.5"	4.5"	7.5"	Bracket required
0354-1100	5.4 quart Universal Clear	8" x 1.4"	Rotating Door	11"	4.5"	10.5"	Bracket Required
0354-1500	5.4 quart Universal RED	8" x 1.4"	Rotating Door	11"	4.5"	10.5"	Bracket Required
0320-1500	2 Gallon Nestable RED	5.6" x 2.3"	Slide	10.3"	7.0"	10.1"	Free Standing

Indications for Use:

Oak Ridge Products Sharps containers are single-use, disposable, non-sterile containers intended to be used for healthcare purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target population is for trained healthcare professionals.

The 1 quart Phlebotomy container is intended to be used with an appropriate mounting device.

The 5.4 quart is intended to be used with an appropriate mounting device.

The 2 gallon container is intended to be used in areas where there is no unsupervised patient access.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.06.20 15:18:41 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____